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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,214	06/14/2001	Michael Probst-Kepper	L0461/7102	6577

7590 12/03/2003

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EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,214	PROBST-KEPPER ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- Th MAILING DATE of this communication appears on the cover she t with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continuation of Disposition of Claims: Claims pending in the application are 1-3,7,8,11,12,18,19,21,22,25-28,33,34,40,41,45,46,48,49,58 and 59.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-3,7,8,11,12,18,19,21,22,27,28,33,34,40,41,45,46,48,49,58 and 59.

DETAILED ACTION

1. Applicant's amendment filed 3/1/01 is acknowledged and has been entered.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1, 2, 3, 7, 8, 58 and 59 drawn to a an antigenic polypeptide/composition/vaccine composition thereof

II. Claims 11 and 12, drawn to an isolated nucleic acid encoding an immunogenic polypeptide

III. Claims 18 and 19, drawn to a method for selectively enriching a population of CD8+ T lymphocytes

IV. Claims 21 and 22, drawn to a method for diagnosing a disorder

V. Claims 27 and 28, drawn to a method for treating a subject having a disorder, comprising administering an immunogenic polypeptide,

VI. Claims 33 and 34, drawn to a method for treating a subject having a disorder comprising administering autologous CD8+ lymphocytes

VII. Claims 40 and 41, drawn to an isolated polypeptide that binds an immunogenic polypeptide

VIII. Claims 45 and 46, drawn to an isolated CD8+ lymphocyte

IX. Claims 48 and 49, drawn to an isolated APC

3. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Independent claim 40 of the instant application does not provide a technical feature that is distinguished over the prior art, as evidenced by Paul et al (page 553) and the instant specification on page 10 at lines 25-26. Claim 40 recites "An isolated polypeptide which binds

selectively the polypeptide of claim 2, provided that the isolated polypeptide is not an HLA class I molecule."

Paul et al teaches that the MHC class II binds immunogenic peptides, and the specification on page 10 at lines 25-26 discloses, "Additional immunogenic peptides derived from the alt.M-CSF polypeptide may provoke an immune response when presented by HLA class I or class II molecules. The invention embraces all such immunogenic fragments of the alt.M-CSF polypeptide." As such, MHC class II is an isolated polypeptide which binds selectively the alt.M-CSF immunogenic peptides such as the functional variant recited in instant claim 2.

Therefore, the instant invention lacks Unity of Invention.

4. **If Applicant elects Group I**, Applicant is further required to (1) elect a single disclosed species (a ***specific polypeptide***, for example, SEQ ID NO: 5) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

5. **If Applicant elects Group II**, Applicant is further required to (1) elect a single disclosed species (a ***specific nucleic acid sequence encoding a specific polypeptide***, for example, SEQ ID NO: 11) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

6. **If Applicant elects Group III**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (a ***specific agent presenting a specific polypeptide***, for example, an APC contacted with SEQ ID NO: 12) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

7. **If Applicant elects Group IV**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (a ***specific agent specific for a specific polypeptide***, for example, a single disclosed agent specific for SEQ ID NO: 12) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

8. **If Applicant elects Group V**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (a ***specific agent polypeptide***, for example, SEQ ID NO: 12) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

9. **If Applicant elects Group VI**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (a ***specific CD8+ T lymphocyte having a specificity for a specific polypeptide and a specific class I molecule***, for example, SEQ ID NO: 12 and HLA-B*3501) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because they have TCR of different structures and they react to different peptide/MHC complexes of different structure.

10. **If Applicant elects Group VII**, Applicant is further required to (1) elect a single disclosed species (a ***specific polypeptide which binds to the polypeptide of claim 2***, for example, a monoclonal antibody to SEQ ID NO: 12) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because they have different structures.

11. **If Applicant elects Group VIII**, Applicant is further required to (1) elect a single disclosed species (a ***specific CD8+ T lymphocyte having a specificity for a specific polypeptide and a specific class I molecule***, for example, SEQ ID NO: 12 and HLA-B*3501) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because they have TCR of different structures and they react to different peptide/MHC complexes of different structure.

12. **If Applicant elects Group IX**, Applicant is further required to (1) elect a single disclosed species (a ***specific APC which comprises a specific specific polypeptide and a specific class I molecule***, for example, SEQ ID NO: 12 and HLA-B*3501) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because they display different peptide/MHC complexes of different structure which can elicit differently restricted and specific immune responses.

13. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

14. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

15. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

16. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

17. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

19. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 703-308-0061 (after 1/7/04 the telephone number is 571-272-0842). The Examiner can normally be reached on Monday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 (before final) or 703-872-9307 (after final).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
December 1, 2003

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
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